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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,342	08/23/2005	Masatsugu Suzuki	266223US0PCT	3642
22850	7590	06/06/2007		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER HUYNH, PHUONG N	
			ART UNIT 1644	PAPER NUMBER
			NOTIFICATION DATE 06/06/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/525,342	SUZUKI, MASATSUGU	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/19/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-9 are pending.
2. Applicant's election with traverse of Group 1, Claims 1-9 drawn to anti-idiotypic antibody which is capable of binding to a first antibody against a first antigen, characterized by comprising: a fused antigen including a substance which is capable of binding to an antigen-binding site of the first antibody and a second antigen, the substance being ligated to the second antigen; and a second antibody which is capable of binding to the second antigen, the substance which is capable of binding to the antigen-binding site of the first antibody comprises a protein, a peptide and a method of producing said anti-idiotypic antibody, filed 3/8/07, is acknowledged. Applicant request that the Examiner expand the search to include the non-elected claims of Groups 2-5, claims 3-9, if the elected Group I is found allowable.

Upon reconsideration, Groups 2-5 have been rejoined with the elected Group 1.

3. Claims 1-9 are being acted upon in this Office Action.
4. Claims 2-4 and 6-8 are objected to because "A" should have been "The" for said dependent claims.
5. 35 U.S.C. 101 reads as follows:
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 1-4 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter, a product of nature.

As written, claims read on whole, naturally occurring anti-idiotypic antibody. Amending the claim to show hand of man, such as "an isolated anti-idiotypic antibody" would obviate this rejection.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** for (1) the binding specificity of all anti-idiotypic antibody, (2) all the second antigen and (3) and the binding specificity of all second antibody to all second antigen for the claimed method.

The specification discloses only a method of screening an anti-idiotypic antibody which is capable of binding to a first antibody against a first antigen by preparing a first antigen which is capable of binding to the antigen binding site of the first antibody; ligating said antigen to either a histidine-tag or a biotin to produce a fused antigen comprising His-Tag fused to antigen or biotin fused to antigen; attaching said fused antigen to an anti-His-tag antibody which is capable of binding to His-Tag or an anti-biotin antibody which is capable of binding the biotin to a solid support; screening antibody that binds to the first antibody against the first antigen and then isolating the antibody that binds to said first antibody against said first antigen as being an anti-idiotypic antibody. The specification also discloses the first antigen to which the first antibody binds could be an epitope of a first antigen, a protein, a peptide, a carbohydrate, a lipid, a nucleic acid or a mixture thereof. The specification discloses the antigen fused to a histidine-tag or a biotin via a spacer such as serine-serine.

The specification does not adequately describe the binding specificity associated with the six CDRs of immunoglobulin heavy and light chain of all anti-idiotypic antibody as broadly as claimed without any description about the first antibody that binds to the first antigen or substance. Further, it is not clear which characteristic of the first antigen or substance in claim 1 is or is not part of the claimed anti-idiotypic antibody.

Further, the specification fails to describe the structure associated with function of the "second antigen" other than the His-Tag and biotin that were used to fuse to the first antigen. The specification also does not adequately describe the binding specificity of all "second antibody" that binds to all second antigen for the claimed method.

The specification does not adequately describe the structure such as CDRs 1-3 of immunoglobulin heavy and light chains associated with the binding specificity of all first antibodies and second antibody as broadly as claimed.

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The specification discloses only a method of screening an anti-idiotypic antibody which utilize only His-Tag and biotin as the substance and antibody to said His-tag and anti-biotin to immobilize the first antibody binding to a first antigen for screening anti-idiotypic antibody that binds to said first antibody.

As such, the anti-idiotypic antibody, substance and second antibody are not adequately described. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co.* 43 USPQ2d 1398; *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC2004).

Applicant is directed to the Final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are:

Claim 5 is incomplete because the essential steps are omitted. The omitted steps are: screening antibody that binds to said first antibody against said first antigen and isolating the antibody that binds to said first antibody against said first antigen as being an anti-idiotypic antibody. It is suggest that claim 5 be amended to recite "A method of screening an anti-idiotypic antibody which is capable of binding to a first antibody against a first antigen, the method comprising: preparing an antigen which is capable of binding to the antigen binding site of the first antibody; ligating said antigen to a histidine-tag or a biotin to produce a fused antigen comprising His-Tag fused to antigen or biotin fused to antigen; attaching said fused antigen to an anti-Histag antibody which is capable of binding to His-Tag or an anti-biotin antibody which is capable of binding to biotin; screening antibody that binds to said first antibody against said antigen and isolating the antibody that binds to said first antibody against said first antigen as being an anti-idiotypic antibody". The remaining claims are rejected for depending from the rejected claim 5.

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Claim 9 is incomplete for failing to recite the essential steps and thus it is not clear how the claimed method improves over the prior art method without reciting what the method steps are in the claim.

11. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "characterized by...binding to the second antigen." in claim 1 is indefinite and ambiguous because it is not clear if the anti-idiotypic antibody or the first antigen comprising: a fused antigen including a substance which is capable of binding to an antigen-binding site of the first antibody and a second antigen, the substance being ligated to the second antigen; and a second antibody which is capable of binding to the second antigen. Further, the "substance" in claim 1 at line 3 has no antecedent in claim 1 at line 2. The remaining claims are rejected for depending from the rejected claim 1.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Dample et al (J Immunoassay 19(2-3): 145-65, May-Aug 1998; PTO 892).

Claims 1-4 are interpreted as an anti-idiotypic antibody which is capable of binding to a first antibody against a first antigen. This is because the clause following "characterized by" merely describes the characteristic of the antigen and has nothing to do with the specificity of the claimed anti-idiotypic antibody.

Dample et al teach an anti-idiotypic antibody such as 757-4-1 which is capable of binding to a first antibody such as chimeric BR96 that binds to a first antigen which is a single chain fusion protein that comprise variable regions of the chimeric BR96 antibody fused to a second antigen such as Pseudomonas Exotoxin A(PE40) via a spacer such as peptide bond. Claim 2 is included in this rejection because the reference substance, which is the tumor cell expressing Lewis antigen inherently capable of binding to the antigen binding site of the first antibody such

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as BR96 chimeric antibody. Claim 3 is included in this rejection because reference antigen is a protein. Thus, the reference teachings anticipate the claimed invention.

14. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat No 6,140,091 (issued Oct 2000; PTO 892).

The '091 patent teaches immunizing an animal such as mice with the variable region of antibody such as the anti-MOPC 167 idiotype antibody Fab fragment linked to KLH (see col. 12, line 66 bridging col. 13, lines 1-2, in particular), and then immunizing mice three days later with antigen in PBS (see col. 13, lines 1-3, in particular). Because claim 9 is incomplete for failing to recite the essential steps, and thus it is not clear how the claimed method improves over the prior art as admitted on record. Therefore, the claim is interpreted as a method of making idiotype antibody (first antibody) which is known in the art based on the network theory that anti-idiotypic antibody is essentially an image of the original antigen and it can serve as an analog of the original antigen to elicit second generation antibody (see col. 5, lines 34-37, in particular). Thus, the reference teachings anticipate the claimed invention.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.

17. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Phuong Huynh/

Patent Examiner

Technology Center 1600

May 28, 2007